

# Evaluation of Coriolis® microbial air sampler coupled with RMM

## Alternative solution for rapid airborne contamination control



### Abstract

For environmental contamination control in cleanrooms, Bertin Technologies (France) has developed a technology dedicated to the monitoring of airborne particles. The goal is to propose a **sampling method compatible with Rapid Microbiological Methods (RMM)** in order to get reliable & specific data and tackle the impact on pharmaceutical production of time-to results within impaction method. This microbial air sampler has been validated according to ISO14698-1 in terms of physical and biological efficiencies (HPA study – July 2008) : the results show the Coriolis® µ is as efficient as the traditional method and even better for high particles diameter (results available on www.coriolis-air-sampler.com). AES Chemunex has also validate a protocol coupling Coriolis® µ with ScanRDI® (cytometry) and allows to get the results in only 3 hours (from sampling step to results). This study aims at completing this data and at testing different RMMs on the samples collected with Coriolis® µ.

### Context



The **microbiological quality control of environments** aims at ensuring the **quality of products** in case of cleanrooms production / ensuring **health and safety** of workers and exposed people. Accurate & reliable measurements of microbial contamination depend on the choice of an adapted air sampler / a representative sample from the controlled environment / the limitation of losses due to a failure of the sampler to capture particles containing micro-organisms or to due to inactivation of viable micro-organisms during collection so that formation of visible colonies on agar surfaces will not occur.

→ **Objective** : realize the feasibility study of the Coriolis® µ air sampler coupled with RMM (Scan RDI) in order to implement it as a **new solution for rapid investigation** in case of contamination and for **routine monitoring in production sites**.

### Material & methods

The air sampling has been carried out in one of the Micro Lab using either traditional air sampler (impactor) or Coriolis® µ. Samples collected with the Coriolis® µ were further processed by filter-plate or ScanRDI method (RMM).

#### AIR SAMPLERS = impactor vs Coriolis® µ (Bertin Technologies)

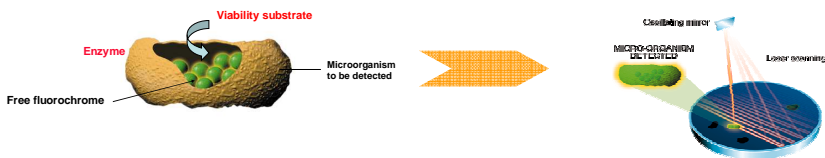
The Coriolis®µ air sampler is based on a patented **cyclonic technology**: it concentrates airborne particles into a liquid collection media.



Coriolis® µ, Bertin Technologies

#### ANALYSIS METHOD = ScanRDI (AES Chemunex)

The ScanRDI® is based on cytometry and uses a double discrimination key : viability and cell membrane integrity.



### Results

**Experiment A** = comparison of Coriolis® µ and impactor (table 1)

- Different areas controlled, equipments placed side by side, 2 replicates
- Filtration of the whole sample from Coriolis® sampling (0,45µm filter) + filter placed on TSA agar plate
- Incubation of plates 20-25°C for 72-96h + 30-35°C for 48-72h

**Experiment B** = Coriolis® µ sampling and ScanRDI detection (table 2)

- Each liquid sample from Coriolis® splitted in A&B aliquots
- A = filter plate method
- B = filtered and analysed with ScanRDI

Table 1 - the impactor and Coriolis® µ give equivalent results on the air samples in the lab.

Samples	Impaction	Coriolis® + filter plate
Biohood	0	1 M
Biohood	0	0
Counter top 2	6 (4 M + 2 B)	2 B
Counter top 2	4 (2 M + 2 B)	1 M
Counter top 3	6 (3 M + 3B)	8 (7 M + 1 B)
Counter top 3	2 B	6 (3 M + 3 B)

M = Mold – B = Bacteria

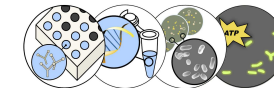
Table 2 - ScanRDI analysis gives higher counts than the filter-plate method does, especially for contaminated air samples.

Samples	Coriolis® + Scan RDI	Coriolis® + filter plate
Biohood	0	0
Biohood+hands	1	0
Counter top 3	9	2 (1 M + 1 B)
Counter top + walking	66	7 (3 M + 4 B)
Counter top + hands	103	8 B

These higher results are partly due to the **viable but non-culturable (VNC)** microbials present in the air which can not be detected with traditional impaction method although they can be pathogen.

### Discussion

**Liquid sample → Access to alternative methods → Rapid results (RMM beyond cultivable flora)**



The Coriolis® system is an easy to use portable air sampler that collects air samples into liquid media. This **allows quick microbial detection when coupled with RMM technologies** as demonstrated into this study.

The feasibility study conducted in Saint-Louis Micro Lab indicates that Coriolis® system collects airborne microorganisms in comparable amount to the impaction system does. ScanRDI can be used as Rapid Microbiology Method coupled with Coriolis® collection in order to give rapid results (around 3 hours from sampling to result). It is also shown here that the amount of microorganisms detected with the ScanRDI is higher than with the traditional method as far as it is not based on cultivability but on viability; appropriate alert and action limits may thus need to be re-evaluated for ScanRDI results. This couple of innovative methods fits for the Environmental Monitoring application and could be implemented **for investigation and routine monitoring** in production sites and in critical areas and **cleanroom environments**.

### Acknowledgement

- Pfizer study Team: Dr Lin Chen (responsible of the study), S. Fennell, W. Snapp
- Bertin Technologies: Alexandra Guerin, Quiterie Desjonquères
- AES Chemunex: Pierre Barbez